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09/683,264	12/05/2001	Michael A. Siani-Rose	3407.2	1024

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EXAMINER

MAHATAN, CHANNING

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 12/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/683,264

Applicant(s)

SIANI-ROSE ET AL.

Examiner

Channing S Mahatan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
4a) Of the above claim(s) 1-11, 20-30 and 39-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-19, 31-38, and 50-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-57 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1 Sheet. 6) ☐ Other: _____

DETAILED ACTION

APPLICANTS' ELECTION

Applicants' election without traverse of Group II (claims 12-19, 31-38, and 50-57; drawn to a computer implemented method, system, and computer software product for gene characterization is acknowledged. Claims 1-11, 20-30, and 39-49 are withdrawn from examination as not directed to the elected invention.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 12-19, 31-38, and 50-57.

Claims Rejected Under 35 U.S.C. § 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

LACK OF ENABLEMENT

Claims 12-19, 31-38, and 50-57 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 U.S.P.Q. 546 (B.P.A.I. 1986) and reiterated by the Court of Appeals in In re Wands, 8 U.S.P.Q. 2d 1400 at 1404 (C.A.F.C. 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3)

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the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

Claims 12-19, 31-38, and 50-57 are rejected under 35 U.S.C. § 112, first paragraph. Claims 12 (line 5), 31 (line 6), and 50 (line 7) recites the step “automatically establishing criteria for assigning the sequences for each model”. Further, dependent claims 17-19, 36-38, and 55-57 recite the limitations “wherein the step of automatically establishing comprises determining a threshold for each of the models” (claims 17, 36, and 55), “wherein the step of determining a threshold comprises performing a curve analysis” (claims 18, 37, and 56), “wherein the step of performing a curve analysis comprises determining a point where the e-value curves drops abruptly or flattens” (claims 19, 38, and 57). However, the specification fails to disclose any steps/procedures for the automatic establishment of criteria for assigning the sequences to each model. Instead, the specification teaches five predetermined criteria for the assignment of sequences to each model. The specification discloses the following:

“Assigning annotations based on SCOP family with distsieve (805). A correspondence between a SCOP family and a gene was based on the E-value scored by SAM-T99. The program distsieve (attached computer program listing) examined all the sequences scored against a particular SCOP model. Because the interpretation of distance scores, expressed as logarithmic E-values was dependent upon the HMM generated for each sequence, there is no single E-value threshold that can be applied to all models. Instead, for each HMM, the distsieve method examined the set of

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scores by curve analysis to determine a reasonable E-value threshold. The distance scores included controls representing the proteins used to build all the models; thus, the best hit was often the seed sequence for the HMM.” (pages 15-16, beginning on line 30)

“In preferred embodiments, the threshold analysis is performed with a curve analysis. In a particularly preferred embodiment, five criteria are used to distinguish the hits to be kept: (1) when the E-values rise above a value of e-05 they are discarded regardless of the other criteria; (2) the first ten hits are kept provided they score better than e-05; (3) the hits more than 70% of the log of the maximum score are automatically kept; (4) the point where the E-value plot drops abruptly or flattens is used as a threshold; (5) no more than a maximum number of hits (e.g., 1000) are kept.”

(pages 12-13, beginning on line 25)

Thus, the specification exemplifies that the thresholds or criteria are not automated, rather given selected thresholds certain hits are retained or discarded automatically. However, this is not synonymous with the instant claim limitation and no guidance is presented on how to do what is claimed. For clarification, the limitation within the instant claim(s) is interpreted to indicate the computer-implemented method, system, and computer program product performs an automated function of determining criteria (i.e. randomly or from some set of “unknown” data) which is then use in assigning the sequences to the models. Further, while the specification does state five specific criteria (which are used to distinguish hits to be kept), absent are procedures to determine/select for these five specific criteria or any other criteria (i.e. basis to keep or not to keep the first hundred hits). One skilled in the art would be required to perform further undue experimentation to formulate procedures that would allow the computer implemented method, system, and computer program product to perform the automated establishment of criteria and identify specific criteria to be established. No guidance, direction, or examples are

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provided such that one of ordinary skill in the art would have known how to make and/or use the claimed invention.

Claims Rejected Under 35 U.S.C. § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-19, 33-38, and 52-57 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

VAGUE AND INDEFINITE

Claims 14-16, 33-35, 52-54, and all claims dependent therefrom recites the limitation “at least 50/150/500 protein sequences are predicted protein sequences” which is vague and indefinite. The claim, as written, makes it unclear if the number of protein sequences represents a limitation which is to be applied to the generated libraries of models (i.e. models of proteins) or to the inputted plurality of protein sequences. Clarification of the metes and bounds, via clearer claim language, is requested.

Claims 19 (line 2), 38 (line 2), and 57 (line 2) recites the limitation “where the e-value curves drops abruptly or flattens” which is vague and indefinite. The terminology of “drops abruptly” or “flattens” implies an assessment quality by way of numerical range of values/criteria that indicates dropping abruptly or flattens with regard to the e-value curves. Applicants can resolve this issue by particularly pointing out the numerical range of values/criteria that indicates e-value curves dropping abruptly or flattening. Clarification of the metes and bounds, via clearer claim language, is requested.

OBJECTION OF DISCLOSURE

The disclosure is objected to because of the following informalities:

The specification, for example on pages 2 (lines 23 and 24), 6 (lines 12, 13, and 14), 7 (line 1), etc., contain embedded hyperlinks which are objected to. Embedded hyperlinks and/or other form of browser-executable code are impermissible in the text of the application as they represent an improper incorporation by reference. See M.P.E.P. § 608.01 and 608.01(p). Applicants are requested to review the application for embedded hyperlinks and/or other forms of browser-executable code and delete them. It should be noted the following is an example of a hyperlink citation that would not result in a browser-executable code is: "World Wide Web Address: scop.berkeley.edu".

Appropriate correction is requested.

No claims are allowed.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Channing S. Mahatan whose telephone number is (703) 308-

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2380 (until 12 January 2004) and (571) 272-0717 (after 12 January 2004). The Examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date: *December 23, 2003*

Examiner Initials: *CSM*

Marianne P. Allen

MARIANNE P. ALLEN
PRIMARY EXAMINER

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